

**REMARKS**

**Status of the Claims**

Claims 90-96, 98-126 and 128-167 are currently pending in the subject application. By this amendment, Claims 90 and 167 have been amended without prejudice or disclaimer, and Claims 173 and 174 have been added to define the invention in another form. Thus, upon entry of this Amendment, Claims 90-96, 98-126, 128-167, 173 and 174 will be pending in the subject application.

Claims 90 and 167 have been amended for clarification purposes to specify that the metering occurs in the holding chamber and to specify that the overflow chamber is disposed between the pump and the holding chamber. Support for these amendments can be found in FIG. 2, in FIG. 5, in the corresponding text and elsewhere in the subject application. No new matter has been added. Applicants assert that no new issues have been raised requiring further search or consideration.

**May 8, 2008 Examiner Interview**

Applicants would like to thank Examiner Alexander for the personal interview conducted on May 8, 2008. In compliance with M.P.E.P. § 713.04, the substance of that interview is reflected in the May 12, 2008 Interview Summary and in the following remarks.

During the interview, amendments and arguments were discussed that would overcome the 35 U.S.C. §112, second paragraph rejections, over claims 90 and 108. Additionally, it was agreed that upon further prosecution the 35 U.S.C. §112, second paragraph, rejections over claims 120, 121, 128-130 and 133 may be vacated. Finally, amendments were discussed that the Examiner indicated appeared to overcome the prior art. Specifically, an amendment to Claim 90 to include the language “wherein the overflow chamber is disposed between the pump and the metered sample” or to specify that “air is pumped through the overflow chamber to the metered sample” appeared to overcome the prior art, although such amendments might not be entered after final.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 108, 119-121, 128-130 and 133 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Preliminarily, clarification as to the status of Claims 90 and 167 is kindly requested. Although the Office Action refers to Claims 90 and 167 on page 2 as being rejected under 35 U.S.C. §112, second paragraph, the Office Action also indicates on page 5 that “Applicants’ amendments and remarks [in the November 28, 2007 response] were convincing to overcome the 35 USC 112 second paragraph rejections of claims 90.” Presumably, for similar reasons, Applicants arguments in the November 28, 2007 Response were also sufficient to overcome the rejection of Claim 167, which is similar to Claim 90. For the same reasons, the withdrawal of the rejection of Claim 167 under 35 U.S.C. §112, second paragraph, is requested.

Clarification concerning Claim 121 is also requested. In Applicants’ previous response, Claim 121 was amended, as suggested by the Examiner, to recite that the method further comprises “adding a predetermined amount of reagent in the holding chamber.” Accordingly, it is Applicants’ understanding that the rejection of Claim 121 under 35 U.S.C. §112, second paragraph, should have been withdrawn. The January 30, 2008 Office Action, however, maintains the rejection of this claim and indicates that the claim could be clarified if “adding a predetermined amount of reagent to the holding chamber” were claimed. The withdrawal of this rejection is respectfully requested.

Concerning Claims 108, 119-120, 128-130 and 133, the Office has maintained that “base claim 90 is directed to a method and Claims 108, 119-121, 128-130 and 133 are directed to structural limitations which do not further limit the method of use.” (page 5). Applicants respectfully disagree. While the Office may determine, for novelty purposes, that it will not analyze purely structural claim limitations in a claim that depends from a method claim, Applicants submit that it does not follow that such claims are indefinite under 35 U.S.C. §112, second paragraph. On the contrary, the claim limitations in each of these dependent claims further limits the respective base claim and are clear on their faces. In addition, Applicants assert

that each of the limitations added by these claims, even if deemed structural in nature, impact the process of the base claim. The withdrawal of these rejections is respectfully requested.

Claims 108 and 119, for example, incorporate all of the limitations of base claim 90 and further require that the holding chamber (Claim 108) or overflow chamber (Claim 119) is corona treated. This constitutes a further limitation to base claim 90.

Claim 120 includes all of the limitations of base claim 90 and adds the additional limitation that the holding chamber comprises a lower interior-surface-to-volume ratio than the overflow chamber. Accordingly, Claim 120 further limits the subject matter claimed in base Claim 90. In addition, the claimed “lower interior-surface-to-volume ratio” has inherent process implications on the process claimed in base Claim 90, and in particular, to steps (a) and (b) thereof. Accordingly, it is respectfully submitted that Claim 120 further limits independent Claim 90 from which it depends and is proper.

Claims 128-129 stand rejected as allegedly not being clear how this further limits the method of Claim 90 and what is the electrochemical species. Applicants respectfully traverse this rejection. The electrochemical species is a molecule that is electroactive, e.g., which can participate in a redox reaction at an electrode. This term is widely understood in the electrochemical art and there is extensive discussion in the section entitled Thrombin-substrate Reaction, starting on page 19, of the subject application. Accordingly, the withdrawal of this rejection is respectfully requested.

Claim 130 includes all of the limitations of base Claim 90 and adds the limitation that the reagent comprises an enzyme substrate deposited at more than one site within the analysis location. Accordingly, Claim 130 further limits the subject matter claimed in base Claim 90. In addition, the claimed additional limitation has inherent process implications on the process claimed in base Claim 90, and in particular, to step (d) thereof. Accordingly, the withdrawal of this rejection is requested.

Claim 133 stands rejected as allegedly not being clear how this further limits the method of Claim 90, what the matrix is or how dissolution is promoted. Applicants traverse this rejection and direct the Examiner’s attention to the section entitled “Reagents” on page 19 of the

subject application, which discusses rapid redissolution of dried reagents. From this discussion, one skilled in the art would recognize that various matrix materials (examples of which include the enumerated polymers and gelatin) may be included in the reagent. In addition, Claim 133 includes all of the limitations of base claim 90 and adds the additional limitation that the reagent comprises a matrix that promotes rapid dissolution into the sample. Accordingly, Claim 133 further limits the subject matter claimed in base Claim 90. The withdrawal of this rejection is requested.

#### Double Patenting

Claims 90-126 and 128-167 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-107 and Claims 1-47 of U.S. Patent Nos. 6,750,053 and 6,438,498, respectively. Upon an indication that the pending claims are otherwise in condition for allowance, Applicants will file a terminal disclaimer in order to obviate this rejection.

#### Rejections Under 35 U.S.C. §§102(b) and 103(a)

Claims 90-105, 107, 109-118, 123, 131-135, 144-145 and 167 stand rejected under 35 U.S.C. §102(b) as being anticipated by Handique et al. (USP 6,103,098). Claims 124-126, 136-143 and 146-166 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Handique et al. Applicants respectfully traverse these rejections in view of the amended claims.

The invention of pending Claim 90 is directed to a method of detecting a reaction product in a sample of blood or blood derivative using a cartridge that includes a holding chamber, an overflow chamber disposed between a pump and the holding chamber, an analysis location, a pump, a reagent and a sensor, the method comprising the steps of: (a) introducing the sample into the holding chamber in the cartridge; (b) metering a portion of the sample by retaining excess sample in the overflow chamber; (c) moving the metered sample from the holding chamber to the analysis location by means of the pump; (d) mixing the metered sample with the reagent in the analysis location; (e) allowing the reagent to form the reaction product in the sample; (f) after the mixing step, positioning the sample at the sensor in the analysis location using the pump; (g) detecting the reaction product at the sensor; and (h) sealing the holding chamber with a closable

sample entry port after step (a). Independent claim 167 is directed to a method of assaying an enzyme in a sample of blood or blood derivative using a cartridge, the method including steps substantially similar to steps (a)-(h) of Claim 90.

As discussed in the May 8, 2008 Examiner Interview, Handique et al., in contrast, teaches an entirely different configuration and method in which overflow material is disposed upstream of the gas intake 50. (See Handique FIG. 3A). That is, the overflow chamber of Handique et al. is not disposed between the gas intake 50 and the metered sample ("L" in FIG. 3A). Since Handique et al. does not teach or suggest every feature of amended Claims 90 and 167, Applicants assert that Claims 90 and 167, and the claims depending therefrom, are allowable over Handique et al.

For the foregoing reasons, Applicants respectfully assert that pending Claims 90-96, 98-126, 128-167, 173 and 174 are in condition for allowance over the references of record, and a Notice thereof is respectfully requested.

Should the Examiner have any questions regarding this response or the application in general, the Examiner is urged to contact the Applicants' attorney, Justin L. Krieger, by telephone at (202) 625-3858. All correspondence should continue to be directed to the address given below.

Respectfully submitted,

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